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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,567	11/13/2001	Christel Schmelzer	1/1171	7734

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,567	SCHMELZER ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-12,15-21 and 28-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-12,15-21 and 28-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on June 28, 2004 wherein claims 1-4, 7-12, 15-21, and 28-46 have been amended; claims 5-6, 13-14, and 22-27 are cancelled.

Currently, claims 1-4, 7-12, 15-21, and 28-46 are pending in this application.

Claims 1-4, 7-12, 15-21, and 28-46 are currently under examination on the merits.

Applicant's amendment amending claim 43, filed June 28, 2004 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of written description of record stated in the Office Action dated December 24, 2003 has been fully considered and is found persuasive to remove. Therefore, the said rejection is withdrawn.

Objection to the Specification

The incorporation of essential material in the specification at page 13, lines 34-36 by reference to a foreign application or patent, or to a publication, i.e., WO 97/12687, is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

See also *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "according to Figures Ia and Ib. " in claim 43 renders the claim indefinite. Each claim must be self-contained. The expression "according to Figures Ia and Ib. " is unclear as to the method encompassed thereby.

The following is the new ground(s) of rejection(s). Therefore, all rejections made under 35 U.S.C. 103(a) of record in the previous Office Action December 24, 2003 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-12, 15-21, and 28-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over FREUND et al. (WO 97/01329 in German, equivalent to US 6,491,897, PTO-892) in view of Hochrainer et al and Wolf et al.(of record).

Freund et al. discloses a propellant free pharmaceutical composition comprising the active agents or combinations of active agents including tiotropium bromide and salmeterol (see 6,491,897, the title, abstract, col.1 line 66 to col. 2 line 15, especially col.2 line 5, 8, 15), which is in a form suitable for inhalation administration, i.e. use in nebulizers (see abstract and col.2 line 1). The pharmaceutical composition of Freund et al. comprises acids such as hydrochloride acid, sulphuric acid, phosphoric acid (see coll.2 line 60-64) which form a pharmaceutically acceptable salts with the active agents, and also comprises adjuvant (see col. 5 line 14-15), and water and ethanol (see col.1 line 40-48) wherein the pH of the solution is in the range of 2-7, especially 3-4 (see col.2 line 66-67), and cosolvent such as isopropyl alcohol, polypropylene glycol, glycol ether (see col.1 line 51-58), and flavoring and ascorbic acid and other adjuvants (see col.2 line 62-64). The propellant free pharmaceutical composition therein is useful in a method of treating obstructive lung diseases such as asthma (see col.1 line 11-15).

Freund et al. does not expressly exemplify the particular combination composition of tiotropium bromide and salmeterol. Freund et al. does not does not expressly disclose the effective amounts of tiotropium bromide and salmeterol. in the composition herein to be administered. Freund et al. does not does not expressly

disclose the compositions therein contained in single preparation or two separate preparations.

Hochrainer et al and Wolf et al teach the claimed tiotropium and salmeterol respectively as old and well known in combination with various pharmaceutical carriers and excipients in both a powder and liquid form useful for atomization. Hochrainer et al. teach tiotropium and other asthma, and COPD medicaments in combination with polyalcohols, (page 5), EDTA (paie 5, line 26), benzalkonium chloride (page 5, line 66), vitamin C (page 4, line 58). These compositions are taught in the particle size range ((970) page 5, line 10-15) , pH (4970) page 4, line 60-62) and encapsulation schema herein envisioned. These pharmaceutical formulations are taught as useful for treating COPD and asthma, viewed by the skilled adisan as indistinguishable from that use herein claimed.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular combination composition of tiotropium bromide and salmeterol, and to optimize the effective amounts of active agents in the composition herein to be administered, and to store the combination in a single or two separate containers.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular combination composition of tiotropium bromide and salmeterol, since the combinations of active agents including tiotropium bromide and salmeterol in a propellant free pharmaceutical composition is disclosed by Freund et al. Thus, any combinations of active agents including tiotropium bromide and

salmeterol disclosed by Freund et al. would have had the reasonable expectation of success as used in a propellant free pharmaceutical composition for treating obstructive lung diseases such as asthma.

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because tiotropium and salmeterol respectively are old and well known to be used in treating COPD and asthma according to Hochrainer et al and Wolf et al. Thus, the optimization of the known amounts of the known active agents to be administered is considered well within the skill of artisan.

Moreover, one of ordinary skill in the art would have reasonably expected that combining tiotropium and salmeterol both known useful for the same purpose, i.e., treating COPD and asthma, would improve the therapeutic effects for treating the same diseases, and/or would produce additive therapeutic effects in treating the same.

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Further, the patient pack, e.g., a single or two separate containers, is all deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's arguments filed on June 28, 2004 with respect to the rejections made under 35 U.S.C. 103(a) of record in the previous Office Action have been considered but are moot in view of the new ground(s) of rejection above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-12, 15-21, and 28-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/736,264.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a composition comprising tiotropium and salmeterol salts as the instantly claimeed.

Thus, the instant claims 1-4, 7-12, 15-21, and 28-42 are seen to be anticipated by the claims 1-20 of copending Application No. 10/736,264.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
February 4, 2005